

All About Nutrition & Health Claim:

GSR 664 VS CODEX Perspective

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With GSR 664 being implemented under prevention of "Food Adulteration Act 1954", label claims are approved in India. Thus it is very important to know all about Nutrition and Health claims. There are a number of international regulations and governing bodies that regulate the use of claims on foods. They are FOSHU (Japan), EU guidelines, the Federal Food, Drug and Cosmetics Act (USFDA) and CODEX.

Today Food is governed by prevention of food adulteration act 1954 and PFA rules 1955. Now GSR 664 defined some label claims, it is important to understand the definition of 'Food' under PFA act before touching claim part of the topic.

Food" means any article used as food or drink for human consumption, other than drugs and water. Thus PFA's definition is very vague and open to interpretation.

FSSA 2006 has given very detailed definition of food.

Food means any substance, whether processed, partially processed or unprocessed, which is intended for human consumption and includes primary food to the extent defined in clause (zx), genetically modified or engineered food or food containing such ingredients, infant food, packaged drinking water, alcoholic drink, chewing gum, and any substance, including water used into the food during its manufacture, preparation or treatment but does not include any animal feed, live animals unless they are prepared or processed for placing on the market for human consumption, plants prior to harvesting, drugs and medicinal products, cosmetics, narcotic or psychotropic substances. This definition has bigger and wider scope thus all types of food are covered including functional food, Nutraceutical, & health supplements.

Definition of Drug under Drug & Cosmetic act 1946

• Drug " includes

– all medicines from internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation, or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes.

FSSA 2006 has been enacted but rules are not yet formed and thus we are still under PFA regime. Let's focus what GSR 664 has defined about Health claims.

GSR 664 has divided claims in three parts.

1) Nutrition Claim 2) Health Claim 3) Risk reduction claim

1) Nutrition claim : **"Nutrition claim"** means any representation which states, suggests or implies that a food has particular nutritional properties which is not limited to the energy value but include the protein, fat and carbohydrates, vitamins and minerals.

Exa : Food A is high in protein.

2) **"Health claims"** means any representation that states, suggests or implies that a relationship exists between a food or a constituent of that food and health and include the

Nutrition claims which describes the physiological role of the nutrient in growth, development and normal functions of the body.

Exa: Food A is rich in calcium and calcium is good for bone health.

Other functional claims concerning specific beneficial effect of the consumption of food or its constituents, in the context of the total diet on normal function or biological activities of the body and such claims relate to a positive contribution to health or to the improvement of function or to modifying or preserving health, or disease.

Exa: Food A is low GI food. Low GI food helps in sugar management

3) Risk reduction claim relating to the consumption of a food or food constituents, in the context of the total diet to the reduced risk of developing a disease or health – related condition;

"risk reduction" in the context of health claims means significantly altering a major risk factor for a disease or health-related condition

Exa: Food A which is source of soluble fiber when consumed as a part of diet low in saturated fat and cholesterol may reduce risk of heart diseases. (0.75 g of soluble fiber/serving)

One need to be very cautioned before putting this risk reduction claim as it goes towards medicinal benefits.

Though GSR 664 has defined all above nutrition and health claims, still there are many questions about its implementation and efficacy proof..

This part of GSR 664 is based on CODEX guideline and thus let's see in detailed what CODEX has covered under various Nutrition claim and Health claim.

The Codex Alimentarius is a collection of internationally recognized standards, codes of practice, guidelines and other recommendations relating to foods, food production and food safety. Its texts are developed and maintained by the Codex Alimentarius Commission, established in 1963 by the [Food and Agriculture Organization](#) of the [United Nations](#) (FAO) and the [World Health Organization](#) (WHO). **The implementation of Codex standards is voluntary and there is no obligation on the countries to adopt the same.**

There are two texts in the Codex that apply to the use of claims for foods namely the Codex general guidelines on claims and the Codex guidelines for the use of nutrition and health claims.

The general guidelines on claims are based on the principle that food should not be described or presented in a false, misleading or deceptive manner. In the guidelines, claim is defined as any representation which states, suggests or implies that a food has particular characteristics relating to its origin, nutritional properties, nature, production, processing, composition or any other quality.

The guidelines prohibit the use of following types of claims for foods:

- ✓ A claim suggesting that a particular food is an adequate source of essential nutrients except where such claims are permissible as per a Codex standard for well defined product or where the product has been accepted to be an adequate source of nutrients by the appropriate authorities.
- ✓ A claim implying that a balanced diet or ordinary foods cannot be an adequate source of all nutrients
- ✓ A claim that cannot be substantiated
- ✓ A claim suggesting that a food can be used for the prevention, alleviation, treatment or cure of a disease or disorder unless they are in accordance with the Codex standards or guidelines for Foods for Special Dietary Uses or they are permissible under the laws of the country in which they are distributed.
- ✓ A claim that could lead to doubts about the safety of similar foods or arouse fear in the mind of consumer
- ✓ The guidelines also prohibit the use of potentially misleading claims. For the prevention of misleading through claims, the guidelines identify certain conditions/criteria for the use of various types of claims. Such claims are only permitted if the respective conditions attached as listed below are satisfied.

Type of claim / Claim title	Condition / criteria
A food has gained increased or special nutritive value by addition of nutrients	Such claim can be made provided the addition is made based on the nutritional considerations as per the respective Codex guidelines and it is subject to legislation by appropriate authorities
A food has special nutritional qualities by the reduction or omission of a nutrient	Such claim can be made if the reduction of nutrients is based on the nutritional considerations and is subject to legislation by appropriate authorities.
The use of terms such as “natural”, “pure”, “organically grown”, “fresh”, “home made” and “biologically grown”	Such terms can be used only if they are in accordance with the national practices in the country where the food is sold.
A food is a religious or ritual preparation	Such claim can be made provided the food complies with the requirements of the appropriate religious or ritual authorities
Claim that a food has special characteristics when all similar foods have the same characteristics	Such a claim can be made if the fact that all the similar foods also have the characteristics is apparent in the claim
A claim highlighting the non-addition or absence of a nutrient	Such claims must be regarded as nutrition claims and subject to mandatory nutrient declaration as per the Codex Guidelines For Nutrition Labeling

The second text i.e. the guidelines for the use of nutrition and health claims encompass the nutrition and health claims in food labeling and where required, in advertising. These guidelines are applicable to all foods bearing nutrition and health claims. As per these guidelines, unless specifically permitted in Codex standards or national legislation, nutrition and health claims cannot be made on infant foods and foods for young children.

In Codex, claims are broadly classified as **nutrition claims and health claims**.

1) Nutrition claim

It is defined as any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals. The declaration of substances in the ingredients’ list, the mention of nutrients as mandatory part of nutrition labeling or the declaration of nutrients or ingredients as per requirements of national legislation does not fall in the ambit of nutrition claims.

A nutrition claim can further be categorized into a nutrient content claim or a nutrient comparative claim.

A nutrient content claim describes the level of a nutrient contained in a food. Claims like “source of calcium”, “no added sugar” and “free of trans fatty acids” are content claims. The guidelines provide for certain nutrient content claims along with specific conditions to be met for the claim to be employed. For a food, which is low in or free of the nutrient on which the claim is made, the term describing the level of the nutrient should not immediately precede the name of the food but should be in the

form “a low (naming the nutrient) food” or “a (naming the nutrient)-free food”. Example – a salt with low sodium contents shall bear a claim saying “low sodium salt”.

The other type of nutrition claim is nutrient **comparative claim**. A nutrient comparative claim is a claim that compares the nutrient levels and/or energy value of two or more foods. Comparison can involve claims like “reduced”; “less than”; “fewer”; “more than”. Example – “This chewable tablet contains X% more chewable calcium than brand y.”

Comparative claims should be permitted based on the following criteria and considering further preparations required for consumption depending upon the form in which food is sold.

The basic requirement of comparative claims is that the foods being compared should be different versions of the same food or similar foods and the foods being compared should be clearly identified. The food must bear on the label a statement of the amount of difference in the energy value or the nutrient content. The amount of difference related to the same quantity, expressed as a percentage, fraction or absolute value, the complete details of the comparison and the identity of the food(s) to which the food is being compared must be provided in close proximity to the comparative claim. The comparison between the compared foods should be based on a relative difference of at least 25% in the energy value or nutrient content for macronutrients and at least 10% in case of micronutrients in the NRV and a minimum absolute difference in the energy value or nutrient content equivalent to the values specified for content claims like “low” or “a source” in the guidelines. The food label can bear the word “light” if the criteria for the word “reduced” are met and must indicate the characteristics, which make the food “light”.

Health claims.

Health claim is defined as any representation that states, suggests or implies that a relationship exists between a food or a food constituent and health. Health claims must consist of two parts – the information on the physiological role (function) of nutrient or on an accepted diet-health relationship and that on the composition of the product relevant to the function unless the function is not linked to specific constituents of the food. Detailed principles have been developed in the guidelines to decide on the eligibility of a claim as a health claim. The claims fulfilling the set requirements are only permitted.

The health claims should be based on current relevant scientific substantiation and the proof available should be adequate for substantiating the claim. The claim should be accepted by competent authorities of the nation where the product is sold and the claimed effect should be derived from consuming a reasonable amount of the food/food constituent. In case of a claim attributed to a food constituent having a set Nutrient Reference Value, the concerned food shall be a source of / high in / low in / free of the constituent based on the recommended consumption with the conditions for such terms applicable. There should be a validated method of quantifying the food constituent that the claim is based on. The guidelines emphasize on development of clear regulatory framework for qualifying / disqualifying conditions for the use of specific claims. The label of the foods bearing health claims must incorporate all the relevant information for consumers. The label must indicate the amount of nutrient or constituent of the food on which the claim is based along with the target group, if applicable. The proper directions for consumption to obtain the claimed benefit and caution advice for vulnerable groups, where applicable must be provided. The maximum safe intake of the food/constituent, how the food fits within the context of total diet and a statement on significance of maintaining a healthy diet must be displayed on the label.

Health claims can further be grouped into nutrient function claims, other function claims and reduction of disease risk claims.

Nutrient function claim is a claim that describes the physiological role of the nutrient in growth, development and normal functions of the body. Example: “Contains folic acid which contributes to the normal growth of fetus. Food X is a source of/ high in folic acid.” As per the guidelines, this type of claim can only be made on those essential nutrients with established Nutrient Reference Values in the Codex or the officially recognized dietary guidelines of the concerned national authority.

Other function claims – These claims concern specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet on normal functions or biological activities of the body. Such claims relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health. Examples: “Vitamin C helps to enhance body’s natural defense system. Food Y contains x grams of vitamin C.”

Reduction of disease risk claims are claims relating the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition.

Risk reduction means significantly altering a major risk factor(s) for a disease or health-related condition. Diseases have multiple risk factors and altering one of them may or may not have a beneficial effect. The presentation of risk reduction claims must ensure, for example, by use of appropriate language and reference to other risk factors, that consumers do not interpret them as prevention claims. Examples: “Adequate iron intake may reduce the risk of anemia. Food X is enriched with iron.”

The guidelines also identify certain conditions for using claims related to dietary guidelines or healthy diets. The only claims permitted shall be the ones related to the pattern of eating contained in the dietary guidelines officially recognized by appropriate national authority. The words of the claim may be flexible as far as the pattern of eating outlined in the dietary guidelines is clearly conveyed. The foods described, as part of a healthy diet shall satisfy certain minimum criteria for other major nutrients related to the dietary guidelines and not just the selective considerations of certain aspects of the food. The foods should not be represented in a manner indicating that a food in itself will impart health. Lastly the foods may be described as part of a “healthy diet” provided that a statement connecting the food to the pattern of eating described in the guidelines is provided on the label.

To conclude, GSR 664 has given ‘what’ part of Health claims but need to wait till detailed rules formation to know ‘how’ part of Health claims. There are many questions on claims which includes Claim substantiations, Efficacy data, Nutritional trial (clinical trials?) & Claim protocol etc which are not clear today. We can expect in FSSAI rule making all above questions will be answered properly and will have very standard system on making Nutrition & Health claims like USFDA and FOSHU. Thus, developing

regulations with long-term dietary improvements across populations, as their underlying goal will maximize this potential of nutrition labels and health claims.

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